

# EXHIBIT 4

**IN THE UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION**

TRUTEK CORP.,  
Plaintiff,

v.

BlueWillow Biologics, Inc.  
ROBIN ROE 1 through 10,  
gender neutral fictitious names,  
and ABC CORPORATION 1  
through 10 (fictitious names).

Defendants.

**CIVIL ACTION No. 2:21-cv-10312-  
SJM-RSW**

**PLAINTIFF'S EXPERT REPORT OF EDWARD A. LEMMO, Ph.D.  
RESPONSIVE TO AND IN REBUTTAL OF DEFENDANT'S  
OPENING EXPERT REPORT OF MANSOOR M. AMIJI**

## **RESPONSIVE EXPERT REPORT OF EDWARD A. LEMMO, Ph.D.**

### **INTRODUCTION**

I have been engaged by Trutek Corp. as a technical expert in the legal matter of Trutek Corp. ("Trutek") v. BlueWillow Biologics, Inc. ("BlueWillow") currently being litigated in federal court in the Eastern District of Michigan.

By means of discovery, BlueWillow submitted an expert report by Mansoor M. Amiji, Ph.D. setting forth his opinions that claims 1, 2, 6, and 7 of Trutek's U.S. Patent No. 8,163,802 ("the '802 Patent") are invalid. I read and understood Dr. Amiji's report as well as the exhibits that he submitted with the report. Further, I am familiar with the teachings and claims of the '802 Patent.

In light of Dr. Amiji's report, Trutek's lead counsel, Stanley H. Kremen, Esq., asked me to opine on four topics that are related to the Amiji report:

1. The level of skill required by a person having ordinary skill in the art ("PHOSITA") related to the claims of the '802 Patent.
2. The scientific and technical aspects of the "hold" function recited in Elements (b) in claims 1 and 2 of the '802 Patent and why the "hold" function is critical to the patented invention.
3. Enablement of the disclosure contained in U.S. Patent Application Publication No. 2004/0071757 A1 by David Rolf.

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4. Relevance of the commercial success of Trutek's products to nonobviousness of the claims of the '802 Patent.

I am opining on each of the above four topics as a rebuttal to Dr. Amiji's report and the opinions expressed therein.

Regarding my qualifications, I received my B.S. in chemistry in 1973, my M.S. in nutrition science in 1977, and my Ph.D. in nutrition science in 1979. Beginning in 1984 and continuing until 2007, I was responsible for development, strategic planning, and marketing activities related to over-the-counter nutritional and supplemental products for major producers in the field. Since 2007, I have been an independent consumer healthcare corporate consultant. I have had extensive experience related to products somewhat similar in scope and application to products manufactured by Trutek based on the '802 Patent. I am very familiar with products of this type. My resume is attached to this report as an exhibit.

My opinions regarding the four assigned topics follow.

### **1. A Person Having Ordinary Skill In The Art**

A person having ordinary skill in the art ("PHOSITA") is essentially a fictitious individual considered to have a general or working knowledge of the subject matter in question. The operative word in this context is "ordinary." This is a person who does not possess special or distinctive knowledge or capability in a discipline. This person would have a basic skill

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set or talent related to the technology related to the art. In addition, a PHOSITA knows of and understands all the prior art in his field of endeavor prior to the time that he is asked to evaluate the teachings of a patent. He must have sufficient experience in his art so as to be competent to understand and interpret the prior art related to a patent so that he can make and use the invention described and claimed in the patent. A PHOSITA is primarily a technician in his chosen field, and his skills are those ordinarily associated with such a technician. He is not an inventor. However, he is not a robot either. He must be able to understand and interpret the teachings associated with the type of structures and chemical compositions described in a document such as a patent. That document may possess directives for creating a product including the step by step protocol for making or assembling the product. In some instances, a PHOSITA may apply his fundamental skills in a procedure to follow instructions provided by a person possessing extraordinary skill. That extraordinarily skilled person may be a person having an advanced degree in a specific discipline who can educate others in that specific skill.

Having been a college professor for more than 30 years, I have taught numerous students on basic scientific concepts who were either majors in the discipline or students who were non-majors who wanted to gain a working general knowledge or skill. The students who majored in the discipline



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would be expected to reach a level of extraordinary skill. Those who were non-majors were not expected to develop extraordinary skill but were expected to have a working knowledge of the subject matter. Hopefully, the example provided takes the imaginary or fictitious person to a real life individual who has a working knowledge of a subject matter and can understand and interpret the subject matter.

It is important to determine the level of skill of a person who would be considered a PHOSITA with regard to the '802 Patent. It is essential that this person cannot be a person having extraordinary skill in the art. A PHOSITA would not have the same knowledge or motivation to invent as a person having extraordinary skill.

In Paragraph 68 on Page 28 of his report, Dr. Amiji opined on the level of skill, experience, and education of a PHOSITA. He stated that such an individual should have "at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation. Also, a person of ordinary skill in the art may have worked as part of a multidisciplinary team—including a chemical engineer, microbiologist, or polymer chemist—and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the team, e.g., to solve a given problem."

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Having read and understood the teachings of the '802 Patent, I concluded that Dr. Amiji described a person of extraordinary skill in the art and technology of that patent. The level of skill possessed by a PHOSITA is that of a chemical or pharmaceutical formulator. This person would have two related but separate qualifications. First, after reading the '802 Patent, he should be able to create the formulations described in the patent, and then be able to use the formulations as prescribed. Second, the PHOSITA must be positioned in time just prior to effective filing date of the '802 Patent. Based on this second requirement, the PHOSITA could not have read the '802 Patent itself. Based on his knowledge and experience, this person would be familiar with all the ingredients listed in the ten formulations shown in the '802 Patent. He would have the skill and experience to duplicate those formulations once having seen their list of ingredients. He must know enough chemistry and biology to be familiar with cationic agents and biocidal agents. He must have knowledge of the various airborne "harmful particles," such as bacteria, viruses, pollen, and other allergens. He must know enough undergraduate physics to understand electrostatic fields as well as the principles of electrostatic attraction and repulsion, adhesion, and cohesion. To that end, he needs to know of ingredients that are surfactants, thickeners, and binders.

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Based on my knowledge and experience, it is my opinion that this PHOSITA need not possess an advanced degree. Further, he does not even need to possess an undergraduate degree. He must be a technician with several years of experience as a formulator. The key requirement is his acquired experience necessary to create a wide variety of formulations from the class of ingredients disclosed in the '802 Patent.

### **2. The "Hold" Function Described and Claimed in the '802 Patent**

The 802 patent expresses the term “hold” in the claim statements related to the multi-action mechanism of the invention. While the product attracts particulate matter from the airflow before entering the nasal passageway utilizing electrostatic forces, this alone is insufficient to protect the individual from harmful particulate matter entering the body's respiratory system. Holding is a protective concept based on adhesive and cohesive properties. Adhesion of the formulation can be viewed in two ways: first adhesion to the skin of the individual applying the formulation in and around the nasal passageway; and second, adhesion of the particles in the airflow to the formulation itself. Cohesion provides a tackiness that incorporates the concept of adhesion. Adhesion concerns the forces bonding dissimilar molecules together. Cohesion concerns the forces bonding similar molecules together. Adhesion considers particles of opposite charge, and cohesion goes beyond this concept to include particles of like charge. This



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sets up a barrier of impermeability trapping a significant number of these particles outside the nasal passageway. If the formulation is applied to the skin or tissue inside a person's nostrils, the holding function prevents these particles from either being inhaled into the respiratory system or from contacting the skin or tissue directly. Therefore, holding is a critical aspect of the patent claims since the power of the electrostatic forces to attract airborne particles must be enhanced using the principles of adhesion and cohesion. This interaction of the formulation with foreign particles found in the air, by electrostatically attracting and capturing them and then holding them in place, sets up the opportunity for the formulation's ingredients to inactivate them prior to entry into the respiratory system. The formulation contains a cationic agent to attract bioactive particles such as bacteria, viruses and other biologically harmful particulates found in the air. It also contains a biocidal agent that acts to destroy or neutralize the captured bioactive particles.

Essentially, the mechanism of the formulation to carry out the protection it claims to afford the user would be incomplete if the formulation did not have the adhesive and cohesive properties required to hold the particles in place. Attraction by electrostatic forces is enhanced by the holding properties of adhesion and cohesion, and the holding properties set

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up the formulation's biocidal ingredients to inactivate and kill bioactive particles that are held in place by the formulation.

Most harmful airborne particles have a negative electrostatic charge. The formulation is applied to the skin or tissue of the nasal cavities as a thin film. The presence of a cationic agent in the formulation produces a positive electrostatic charge, which attracts and captures the negatively charged particles. A biocide in the formulation would ordinarily be expected to inactivate and kill the captured bioactive particles. But, to be effective, biocidal action requires contact with bioactive particles for a certain time period. If the captured particles happen to dislodge from the formulation's thin film, they would remain active and be inhaled. Even if they were in contact with the biocide for a sufficient time to be inactivated, the dislodged inactivated particles would still be able to be inhaled. Thus the "hold" function is critical to usefulness of the invention.

An analogy would be a mouse trap. If the trap merely attracts a mouse which mounts the trap to eat the cheese, unless the trap can hold and bind the mouse to the trap, the trap would be useless. If the formulation of the '802 Patent merely has a cationic agent to attract airborne bioactive particles and a biocidal agent to inactivate and kill the particles, it would be useless unless it can hold the particles in place long enough to inactivate

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them and to prevent them from entering the respiratory system. The hold function is a critical part of the claimed invention.

### **3. The Rolf Patent Application**

The Rolf patent application discusses the use of essential oils applied to an adhesive patch placed in the vicinity of the nose to act as a biocidal agent against respiratory pathogens. Historically, essential oils have been used for centuries. Their use in modern times relates to aromatherapy. The literature includes references for their use in a variety of conditions. Essential oils are useful in a variety of applications related to cosmetics, natural products, and household products. They are produced by distillation from plant-based sources.

Rolf discusses the role of essential oils acting against bacteria and viruses. The most commonly used essential oils with antimicrobial action are:  $\beta$ -caryophyllene, eugenol, eugenol acetate, carvacrol, linalool, thymol, geraniol, geranyl acetate, bicyclogermacrene, cinnamaldehyde, geranial, neral, 1,8-cineole, methyl chavicol, methyl cinnamate, methyl eugenol, camphor,  $\alpha$ -thujone, viridiflorol, limonene, (Z)-linalool oxide,  $\alpha$ -pinene, p-cymene, (E)-caryophyllene,  $\gamma$ -terpinene.

Some essential oils are effective antimicrobials and have been evaluated for food incorporation *in vitro*. However, actual deployment is rare because much higher concentrations are required in real foods. Some or

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all of this lower effectiveness is due to large differences between culture medium and foods in: chemistry (especially lipid content), viscosity, and duration of inoculation/storage.

The limitations associated with the use of essential oils relate to the amount or concentration of the oil. Reports in the literature suggest essential oils have skin irritating properties when applied, and others suggest more severe toxicity profiles, putting the user at risk for more serious medical problems.

While the patent application suggests a mechanism of biocidal action by using these essential oils applied to a patch and placed in the vicinity of the nose, there is no reference to how this invention attracts and holds the biologic pathogen before entering the respiratory system. Consider the fact that essential oils are used in the production of perfumes, room air fresheners, and in the natural products industry as aromatherapy products. All of these would be of a similar function in acting to destroy pathogens found in the air.

The biocidal action is concentration dependent and specific to the type of essential oil used. The claims in the Rolf patent application for the use of essential oils as a biocidal agent are not related to the '802 Patent because there is no discussion of electrostatic forces attracting airborne particles, the ability of the formulation to hold the airborne particles using adhesion and



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cohesion concepts, or inactivation of the particles using biocidal components.

Furthermore, the patch would not function as described by Rolf. As I mentioned in the last section, to be effective, biocidal action requires contact with bioactive particles for a certain minimum time period. If the particles are not held in place by the patch, they would continue to float around, remain active, and be inhaled. The only adhesive property of Rolf's patch is its ability to adhere to the skin in the region just below the nose. The side of the patch facing the airborne particles has no adhesive properties. The Rolf invention will not work for its intended purpose.

### **4. Commercial Success**

I understand that commercial success of a patented product tends to show that the patented claims are not obvious provided that the commercial success is due solely to the patented claims. Since the time the '802 patent was issued in 2012, approximately seven million units of the product based on this patent, have been sold in the United States and internationally. This clearly is a measure of commercial success. When evaluating commercial success, a key factor is repeat sales of a product and the length of time the product remains on the market. Having been involved in product development for OTC products and as a member of the business development team for a major pharmaceutical company OTC division, I had



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the opportunity to evaluate technologies and products that the company was interested in licensing from an inventor. Also, as a product development scientist, I know the challenges and difficulties to create a unique and effective product. Patent protection offers additional support for a product to be considered as a success. Since the Trutek products have patent protection and have been marketed successfully for ten years, this product line stands tall among products in this category. The product has a domestic and international presence which demonstrates that it has been reviewed for human use without prescription for the claimed properties established in the patent. When marketing in foreign countries, usually the ministry of health of these countries reviews the merits of the product claims before it gets approval for marketing the product to the population.

The commercial success of this product stands on the sales number and the lack of adverse events reported by the user. The '802 Patent claims a product that electrostatically inhibits harmful airborne particles from infecting an individual. The particles might be microbes, pollen, allergens, or mites that float in the air and are usually inhaled. This product effectively prevents that from happening by creating a positive electrostatic charge that attracts the particles and holds the particles in place until a biocide can inactivate them and render them harmless. Trutek does little or no advertising. The products are either sold online or in retail outlets. The

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patent number of the '802 Patent is clearly marked for every unit sold in the United States. Based on what the '802 Patent claims and what the products actually do, I conclude that the commercial success of the products is due solely to the performance and features of the claimed invention of the '802 Patent.

Dated: August 23, 2022

  
Edward A. Lemmo, Ph.D.

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## **EDUCATION**

Ph.D. Nutrition Science, Rutgers University, New Brunswick, NJ (1979)  
M.S. Nutrition Science, Rutgers University, New Brunswick, NJ (1977)  
B.S. Chemistry, St. Francis College, Brooklyn, NY (1973)

## **EXECUTIVE TRAINING COURSES**

Executive Leadership Program, Princeton, NJ  
Time Management Skills, Teaneck, NJ  
Media Communication Skills, New York City, NY

## **EMPLOYMENT EXPERIENCE**

2007-Present      **Consumer Healthcare Corporate Consultant**  
Self-employed Consultant - Consumer Healthcare

2005-2007      **BioBalance Corporation**, New York, NY  
**Vice President, Product Development**

Person primarily responsible for investigating its probiotic product PROBACTRIX™ to be used for treating pouchitis and other gastrointestinal disorders. Probiotic products are an optional alternative to the probiotic Lactobacillus acidophilus. In charge of all scientific product evaluation conducted at company headquarters.

1999-2005      **Wyeth Consumer Healthcare**, Leonia and Madison, NJ  
**Vice President, Product Development**

Division of American Home Products  
Formerly Whitehall-Robbins Consumer Healthcare

Managed product development for SOLGAR®, and contributed towards CENTRUM®, and CALTRATE®, brands. Responsible role in scientific affairs and new business

development opportunities. Further, responsible for evaluation of acquisition of new business entities.

1992-1999

**General Nutrition Centers, Inc.,** Pittsburg, PA  
**Director, Nutritional Sciences**

Analyzed safety of amino acid products for presentation to the FDA and FTC and other U.S. government agencies. Evaluated and made recommendations regarding nutritional and homeopathic products. Performed quality assurance activities related to label claims and product safety. Responsible for introduction of the new PRO-PERFORMANCE sports nutrition product line into the GNC retail marketplace.

In 1993, for Quigley Corporation, I evaluated the safety and efficacy of Cold-EEZE<sup>®</sup> zinc lozenges to be used to shorten a common cold as a possible line of homeopathic products exclusively marketed by GNC.

1989-1992

**Pall Biomedical Products,** Glen Cove, NY  
**Marketing Manager**

Responsible for marketing activities of Intravenous filtration devices, and Heat and Moisture exchange respiratory products. Wrote all scientific evaluation documents related to Heat and Moisture Exchange respiratory product for presentation to anesthesiologists regarding prevention of injury from patients breathing cold dry gas during surgery. Developed scientific presentations, videos, and product marketing material for use by healthcare professionals.

1984-1989

**ICN Pharmaceuticals,** Costa Mesa, CA  
**Director of Nutritional Technology**

**Faraday Laboratories Division**

Product development of nutritional supplements for use by chiropractic and alternative health practitioners throughout the United States and Canada. Product brands included Nutridyn<sup>®</sup> and Sivad Bioresearch<sup>®</sup>. Responsible for new product development, wrote technical literature, and prepared and delivered scientific educational presentations to practitioners at chiropractic colleges and chiropractic meetings.

1976-1977

**Pharmacia Laboratories, Piscataway, NJ  
Clinical Trials Coordinator**

Assisted veterinarian in analysis of equine blood samples. Performed evaluation analysis of HEALON<sup>®</sup> products comprising hyaluronic acid, and their effect on tissues.

**CORPORATE CONSULTING EXPERIENCE**

2011

**Matrixx Initiatives, Inc., Princeton, NJ  
Scientific Affairs Consultant**

Performed research associated with ZICAM<sup>®</sup> oral zinc product. Provided guidance for coordinating research trials. Managed human efficacy clinical trials.

1998-1999

**Church & Dwight, Princeton, NJ  
Scientific Advisor**

Evaluated consumer healthcare products. Explored and determined market for magnesium based organo-metallic agents for use in dietary supplements.

1998-1999

**IVC Industries, Freehold, NJ**

IVC is a contract manufacturer of generic vitamins. Responsible for new product development. Assisted the marketing staff with product label claims.

1996

**Nutrition 21, Purchase, NY**

Company is a supplier to GNC. Performed consulting work regarding their products.

1996

**Nutramerica, Lincoln Park, NJ**

Technical advisor for the development of a dietary supplement product line.



**CORPORATE CONSULTING EXPERIENCE (continued)**

1996                      **American Vitamin, Ramsey, NJ**

Company is a contract manufacturer. Performed new product development and assistance with evaluation of raw materials from India.

**COLLEGE TEACHING EXPERIENCE**

2013-2018              **Touro College, New York City, NY**

Taught in nursing school. Courses included pathophysiology, genetics, anatomy and physiology and tutored microbiology

2008-2014              **University of Medicine & Dentistry of New Jersey (UMDNJ), Newark, NJ**

Taught in nutrition program. Courses included general chemistry, anatomy and physiology, biochemistry, and microbiology.

1977 and                **New York University, New York, NY**

2000-2003              Taught in graduate nutrition program, vitamin and mineral metabolism

2011-2012              **Cedar Crest College, Allentown, PA**

Taught courses in nutritional biochemistry and metabolism.

1984-1989              **University of New Haven, West Haven, CT**

Taught graduate level course in vitamin and mineral nutrition.

1974-1984              **Brooklyn College, CUNY, Brooklyn, NY**  
**Assistant Professor**

Taught nutrition courses to pre-medical and nutrition students.

1973-1977              **Rutgers University, Piscataway, NJ**

Taught general biology lab and mineral metabolism.

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ROBIN ROE 1 through 10, gender  
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(fictitious names).

Defendants.

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CERTIFICATE OF SERVICE

Undersigned hereby states that on August 15, 2022, the attorneys for Plaintiff caused the foregoing document to be served upon all counsel of record, via electronic service.



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